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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/991,209	11/16/2001	Nigel Dunn-Coleman	GC648-2	6062
5100 7590 01/27/2006 GENENCOR INTERNATIONAL, INC. ATTENTION: LEGAL DEPARTMENT 925 PAGE MILL ROAD PALO ALTO, CA 94304			EXAMINER KALLIS, RUSSELL	
			ART UNIT 1638	PAPER NUMBER

DATE MAILED: 01/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/991,209	Applicant(s) DUNN-COLEMAN ET AL.	
	Examiner Russell Kallis	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3,6-12,14,15,18,19,23,25,27-33,75 and 77-92 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3,6-12,14,15,18,19,23,25,27-33,75 and 77-83 is/are allowed.
- 6) ☒ Claim(s) 84-92 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 July 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 84-92 are newly added. Claims 1-2, 4-5, 13, 16-17, 20-22, 24, 26, 34-74 and 76 have been cancelled. Claims 3, 6-12, 14, 15, 18, 19, 23, 25, 27-33, 75 and 77-92 are pending and examined.

Rejection of Claims 3, 6-12, 14, 15, 18, 19, 23, 25, 27-33, 75 and 77-83 under 35 U.S.C. 112 1st, is withdrawn in view of Applicant's amendments.

Rejection of Claims 3, 6-12, 14, 15, 18, 19, 23, 25, 27-33, 75 and 77-83 under 35 U.S.C. 103(a) is withdrawn in view of Applicant's amendments.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 84-92 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 2/17/04, 11/03/2004 and 3/09/2005. Applicant's arguments filed 8/16/04, 2/18/2005 and 6/03/2005 have been fully considered but they are not persuasive.

Applicant asserts that references cited by the examiner disclose ferulic acid esterases (response page 11). Applicant's specification points to SEQ ID NO: 1 encoding an FAE1 amino acid sequence of SEQ ID NO: 2 that bears a closer resemblance at the level of sequence identity to FAE III (see de Vries R. *et al.* Applied and Environmental Microbiology, Dec. 1997; Vol. 63,

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No. 12; pp. 4638-4644 and attached sequence report) than to the amino acid sequence of FAE1, which is encoded by and also known as faeB; see DeVries R. *et al.* (Biochem. J. (2002) Vol. 363, pp. 377-386 and attached GenBank Accession GI: 23821545) who teach isolation of FaeB a second feruloyl esterase from *Aspergillus niger* that encodes FAE1 (see page 377 column 1 line 13 to column 2 line 21 and the Discussion section on page 384 in column 1 the 1st paragraph and on page 385 in column 2 lines 2-4). FAE-III is 281 amino acids in length and FAE1 is 521 amino acids in length; and Applicant's polypeptide sequence of SEQ ID NO: 2 is 281 amino acids in length. Clearly, Applicant has not clarified the description of polynucleotides encoding an FAE amino acid sequence. Although each and every embodiment need not be described, from Applicant's lack of written description of the claimed genus it remains unclear what features identify a ferulic acid esterase or an FAE1 encoding polynucleotide.

Claims 84-92 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for transgenic Festuca, Lolium, Sorghum, Zea, Triticum, Avena and Poa comprising a polynucleotide encoding an ferulic acid esterase enzyme from *Aspergillus niger* of SEQ ID NO: 2 wherein expression of the *Aspergillus* ferulic acid esterase is targeted to the vacuole, ER, golgi apparatus or apoplast, does not reasonably provide enablement for any grass plant comprising an FAE1 encoding polynucleotide or any ferulic acid esterase encoding polynucleotide sequence other than polynucleotide sequence encoding the amino acid of SEQ ID NO: 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. This rejection is maintained for the reasons of record set forth in the Official action

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mailed 2/17/04, 11/03/2004, 3/09/2005 and 8/18/2005 Applicant's arguments filed 8/16/04, 2/18/2005, 6/03/2005 and 11/10/2005 have been fully considered but they are not persuasive.

Applicant asserts that their statement that one could isolate ferulic acid esterases and that ferulic acid esterases were known in the art (response page 11). Applicant has not provided working examples of FAE enzymes sufficient reduce the amount of undue trial and error experimentation that would be required to isolate a polynucleotide encoding an FAE enzyme, and hence reduce the unpredictability in the art. Further, see arguments and art presented previously under written description.

Given the unpredictability in the art as to which ferulic acid esterase encoding polynucleotides would have activity upon a conjugated ferulic acid substrate; the breadth of the claims encompassing a non-exemplified ferulic acid esterase 1 encoding polynucleotide; the lack of guidance in the examples of the specification or in the prior art; undue trial and error experimentation would be needed by one skilled in the art to make and clone a multitude of non-exemplified ferulic acid esterase 1 encoding polynucleotides and would require one of skill in the art to test in a myriad of non-exemplified grass plants for an altered phenotype in a multitude of non-exemplified transformed plant grass species. Therefore, the invention is not enabled for the scope set forth in the claims.

Claim Rejections - 35 USC § 103

Claims 84-92 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson *et al.* U.S. Patent 6,143,543 issued November 7, 2000 in view of Bartolome B. *et al.*, Applied and Environmental Microbiology; January 1997, pages 208-212. This rejection is maintained for the reasons of record set forth in the Official action mailed 2/17/04, 11/03/2004, 3/09/2005 and

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8/18/2005 Applicant's arguments filed 8/16/04, 2/18/2005, 6/03/2005 and 11/10/2005 have been fully considered but they are not persuasive.

The claims are broadly drawn to plants comprising an isolated FAE encoding polynucleotide, wherein the specification circuitously defines an FAE1 encoding polynucleotide as any nucleic acid sequence comprising the coding region of an FAE1 gene or which encodes an FAE1 polypeptide, or that hybridizes under low stringency to a probe of anywhere from 8 to 300 nucleotide of the sequence disclosed in WO 98/14594 also U.S. Patent 6,368,833 that teaches the FAE-III encoding polypeptide from *Aspergillus niger*.

Michelson teaches a polynucleotide encoding a ferulic acid esterase (FAE III) from *Aspergillus niger* in columns 8-9 and methods of plant transformation in columns 16-17 and 21-22, wherein a plant comprising an expression cassette comprising a ferulic acid esterase encoding polynucleotide in plants derived from *Aspergillus niger*, operably linked to a promoter, is taught as an embodiment of the invention and wherein the release of ferulic acid and diferulate dimers from grass cell walls (columns 27-28) inherently teaches the sequence of the targeting sequence from *Aspergillus niger* ferulic acid esterase (see the first non-patent publication listed in references cited, de Vries *et al.*, on page 4640 column 2 and also page 16 of specification); and further teaches the advantages of using the FAE enzyme to alter cell walls of wheat (column 1 lines 1-65), that cereal plants are preferred plants for transformation (column 10 lines 8-9), and the addition of a second gene of interest such as a gene encoding a xylanase may give additional nutritional value to a food or feed or crop (lines 4-24, 50-51 and in column 13 lines 4-7).

Michelson does not teach a polynucleotide encoding a xylanase.

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Bartolome teaches recombinant expression cassettes comprising XylD and XylA (page 208, column 2 in Materials and Methods) and that a xylanase in combination with a ferulic acid esterase from *Aspergillus niger*, together more effectively released ferulic acid from the cell walls of barley and wheat cell walls than either enzyme alone (see page 208, columns 1 and 2).

It would have been obvious at the time of Applicant's invention to modify the invention of Michelson to include an expression cassette comprising a polynucleotide sequence encoding a xylanase, operably linked to a promoter. One of skill in the art would have been motivated by the teachings of Michelson of the genetic engineering of cereal crop plants to express a ferulic acid esterase encoding polynucleotide and motivated by the success of Bartolome in enhancing the release of ferulic acid from cell walls of wheat and barley by a ferulic acid esterase in concert with a xylanase made from recombinant expression cassettes, and that one would have had a reasonable expectation of success of expressing the ferulic acid esterase and xylanase encoding genes in transformed plants; wherein using either an inducible, senescence, heat shock, or constitutive promoter, a KDEL ER retention sequence, and a stop codon are obvious optimizations of design parameters and by Applicant's own teachings in the specification that inducible, senescence, heat shock, and constitutive promoters, the KDEL ER retention sequence, and termination sequences as well as methods of transforming and regenerating transformed plants are well known in the art (see specification pages 19-23).

Applicant asserts that motivation to modify the invention, disclosure of all of the elements of the claimed invention, and a reasonable expectation of success has not been established because the expression cassette as claimed includes a targeting sequence and that stable expression is not taught or suggested (response pages 9-10).

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The *Aspergillus* sequence of the '543 Patent, known in the art, inherently teaches a signal sequence; see the first non-patent publication listed in references cited, de Vries *et al.*, on page 4640 column 2. Further, there is no evidence to suggest that the FAE and the techniques taught in the specification of Michelson would not result in the stable expression of FAE in a transformed *Festuca*, *Lolium*, *Sorghum*, *Zea*, *Triticum*, *Avena* or *Poa* plant.

Applicant asserts that there is no teaching of how recombinant expression of an FAE in grass plants should be accomplished (response page 8). Transformation of plants is provided by the '543 reference. Further, the '543 reference provides motivation to transform cereal plants e.g. *Festuca*, *Lolium*, *Sorghum*, *Zea*, *Triticum*, *Avena* and *Poa* as argued supra. Moreover, methods of transforming cereals and grasses were known in the art see Applicant's specification pages 22-23.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Claims 84-92 are rejected.

Claims 3, 6-12, 14,15, 18, 19, 23, 25, 27-33, 75 and 77-83 are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (571) 272-0798. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Russell Kallis Ph.D.
January 20, 2006

RUSSELL P. KALLIS, PH.D.
PATENT EXAMINER

Russell Kallis